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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,396

10/19/2006

Peter John Meikle

MAYO-0008 US1

3264

25555 7590 10/14/2011
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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

10/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,396	MEIKLE ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-42,51-53 and 56-74 is/are pending in the application.
- 5a) Of the above claim(s) 1-41 and 58-73 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 42,51-53,56,57 and 74 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/17/11,03/22/11, 07/13/11, 09/13/11</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the claims

The amendment filed 07/13/11 is acknowledged and has been entered. Currently, Claims 1-42, 51-53 and 56-74 are pending. Claims 1-41 and 58-73 are withdrawn as being directed to non-elected inventions. Claims 42 and 74 have been amended. Claim 46 has been cancelled. Claims 42, 51-53, 56, 57 and 74 are under examination.

Withdrawn Rejections

All rejections of claims not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 42, 51-53, 56, 57, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 step (g) is vague and indefinite because the instant claims require the detection of multiple targets and it is unclear how one microsphere comprising only one antibody for a specific target is also able to detect the other targets in the assay. Is there more than one type of microsphere or more than one type of antibody? See also

Art Unit: 1641

deficiency found in claim 74. Therefore, it is unclear how the determination of the targets is made in the instantly recited claim.

Claim 42 step (g) is vague and indefinite because it is unclear what relationship exists between the microsphere recited in line 4 of step (g) and "each microsphere recited in line 8 of step (g)". The claim does not make clear if Applicant knows intends additional beads are added to the method or not. Further, the microsphere recited in step (g), line 4 appears to have a single antibody which is capable of binding to α -iduronidase or α -glucosidase or LAMP-1 or saposin C. The recitation of "each microsphere conjugated to a specific capture antibody" and "each microsphere conjugated to a specific capture antibody" causes confusion because it is unclear if the specific capture antibodies are referring to α -iduronidase or α -glucosidase or LAMP-1 or saposin C or if Applicant intends something else. Further, if Applicant intends that only one microsphere is used in the method and wherein the one microsphere is for one target then steps (a) and (b) of the claim would not be accomplished. If Applicant intends that there is a population of microspheres wherein each microsphere has a different antibody (i.e. one microsphere contains a specific capture antibody for α -iduronidase, another microsphere is conjugated with an antibody specific for α -glucosidase, etc) and each microsphere has first and second fluorophores which are spectrally distinct. Then Applicant should clearly recite such limitations in the claim. See also deficiency found in claim 74.

Response to Arguments

3. Applicant's arguments filed 07/13/11 have been fully considered but they are not persuasive.

Applicant argues that the Applicants have amended Claims 42 and 74 to specific that each microsphere conjugated to a specific capture antibody is spectrally distinct from a microsphere conjugated to a different capture antibody.

This argument is not found persuasive because of reasons stated supra it is unclear what relationship exists between the microsphere recited in line 4 or step (g) and "each microsphere recited in line 8 of step (g)". The claim does not make clear if Applicant know intends additional beads are added to the method or not. Further, the microsphere recited in step (g), line 4 appears to have a single antibody which is capable of binding to α -iduronidase or α -glucosidase or LAMP-1 or saposin C. The recitation of "each microsphere conjugated to a specific capture antibody" and "each microsphere conjugated to a specific capture antibody" causes confusion because it is unclear if the specific capture antibodies are referring to α -iduronidase or α -glucosidase or LAMP-1 or saposin C or if Applicant intends something else. Further, if Applicant intends that only one microsphere is used in the method and wherein the one microsphere is for one target then steps (a) and (b) of the claim would not be accomplished. If Applicant intends that there is a population of microspheres wherein each microsphere as a different antibody (i.e. one microsphere contains a specific capture antibody for α -iduronidase, another microsphere is conjugated with an antibody specific for α -glucosidase, etc) and each microsphere has first and second fluorophores

Art Unit: 1641

which are spectrally distinct. Then Applicant should clearly recite such limitations in the claim.

NOTE: The Applicant is encouraged to contact the undersigned to resolve the issues stated supra.

Conclusion

4. No claims are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Melanie J Yu/
Primary Examiner, Art Unit 1641